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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,327	06/21/2001	James Allen McEwen	1077-023-PWH	6889

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IPSOLON LLP  
805 SW BROADWAY, #2740  
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EXAMINER
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BUI, VY Q

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 01/05/2004

7

Please find below and/or attached an Office communication concerning this application or proceeding.

28

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/886,327		MCEWEN, JAMES ALLEN	
	<b>Examiner</b>		<b>Art Unit</b>	
	Vy Q. Bui		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5,6,8-13,15-17,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,8-13,15-17,19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
       Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
       Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 5-6, 11, 13-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over SMITH and NEPHEW RICHARDS' cuff (now is SAMMONS PRESTON ROLYAN, Bolingbrook, Illinois).

Regarding claims 1, 5-6, 11, 13-15 and 18, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee discloses a pair of a tourniquet cuff and a stockinette sleeve and inherently a method of using the pair of the tourniquet cuff and the stockinette sleeve. The pair comprises a tourniquet cuff having a length sufficient for encircling a limb having a limb circumference within a range of not less than a predetermined minimum (cuff overlap about four inches, first page, SMITH and NEPHEW RICHARDS)

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and not more than a predetermined maximum (cuff overlap about three inches, first page SMITH and NEPHEW RICHARDS), and wherein the cuff has a color code thereon that is indicative of that range (see list of color coding on third page, SMITH and NEPHEW RICHARDS' disposable cuffs), a stretchable protection sleeve/stockinette sleeve made of stockinette applied to the limb such that the sleeve circumference should be less than the limb's circumference to avoid any wrinkles in the stockinette sleeve (item 4, page 1, SMITH and NEPHEW RICHARDS), and instrument for pressurize the cuff. SMITH and NEPHEW RICHARDS discloses stockinette sleeve standard on each tourniquet (see third page, SMITH and NEPHEW RICHARDS' disposable cuffs). Inherently, there must be a means (such as a label, a mark, an alphabet code, a color code ...) to indicate a match between a cuff and an associated stockinette sleeve to help a physician to select a right pair of cuff and stockinette sleeve to use on a patient. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made to mark or label a sleeve to match an associate cuff so as to help a physician or a user to identify the right pair of cuff and sleeve for a patient.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 8-10, 12 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over SMITH and NEPHEW RICHARDS, Inc. (now is SAMMONS PRESTON ROLYAN, Bolingbrook, Illinois).

As to claims 2, 12, SMITH and NEPHEW RICHARDS does not expressly disclose same color-coding for a pair of a cuff and an associate sleeve. However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to mark both a cuff and an associate sleeve with the same color to help a user to identify and match quickly a separate cuff and its associate sleeve and avoid a use of a pair a cuff and a unmatched sleeve, which could render a tourniquet procedure less effective.

As to claim 17, SMITH and NEPHEW RICHARDS does not disclose a separate sealed package for a matching pair of a cuff and a sleeve. However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to put a pair of a cuff and an associate sleeve in a package, such as a sealed plastic bag, so as to pre-select the right pair of a cuff and an associate sleeve for a user.

Regarding claims 8-10, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee discloses substantially all limitations as recited in the claims except the manner in which the sleeve is constructed to carry the color code thereon. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to construct the sleeve as claimed for this is just one way to make the sleeve and this construction would make no critical effect to the performance of the device.

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3. Claims 16, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee.

Regarding claims 16, 19-20, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee does not disclose the stockinette sleeve applying a pressure less than a predetermined pressure of 2 mmHg on the limb or maximum pressure to be less than 25mmHg and other features as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make experiments to determine the optimum value predetermined pressure of 2 mmHg to 25mmHg since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

As to claims 21-22, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee discloses substantially the claimed invention. The additional features as recited in the claims are well known. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee device with the additional features as claimed.

### ***Response to Amendment***

The amendment filed on 10/10/2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the cited reference.

It would appear that the device of the reference qualifies for either anticipation 102 rejection or obviousness 103 rejection. The reference does not disclose any specific range of pressure inserted by a stockinet on a limb. However, the pressure exerted by the stockinet on a limb of a patient can be well within the pressure range as

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claimed. The Examiner is not certain that one can claim a novel method when the method has been used in real life, even though a user may do not accurately know a specific range of pressure when the stockinet is applied to a limb.

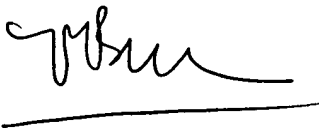
### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. SMITH et al (4,650,475) discloses same color coding of a cuff and a sleeve in a medical device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2708 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



VQB

December 22, 2003